

Physician Open Payments June 30th Data Publication to Incorporate New Final Rule Changes

By Mary Kate McDevitt and Marc S. Raspanti

The Physician Payments Sunshine Act (PPSA) took effect in 2013. It requires medical product manufacturers to disclose to the CMS payments or transfers of value made to physicians or teaching hospitals including meals, travel reimbursement, and consulting fees.¹ Payments related to research are reported through a separate reporting system.² The act also requires manufacturers and group purchasing organizations to disclose any physician's ownership or financial interest in those companies.³

The Process

Data about payments made to covered recipients is collected by reporting entities throughout the year. Data collected during the previous calendar year is submitted to CMS between February 1 and March 31 each year. Covered recipients may review and dispute the data from April 1 until May 15. Reporting entities resolve disputes and correct data from April 1 until May 30. The disclosed data is published by CMS in a publicly searchable database by June 30th each year.⁴ The search tool currently has data from January 2016 until December 31, 2022. The 2023 data will be published on June 30, 2024. Between 2016 and 2022, \$68.42 billion dollars have been reported through Open Payments.

Penalties

Penalties for failure to comply with the act are broken down into two main categories: violation of the PPSA and knowing violation of the PPSA. The penalties as adjusted annually pursuant to 45 CFR §102. Currently, violations of the PPSA are subject to a civil money penalty of not less than \$1,362, but not more than \$13,625, for each payment or other transfer of value or ownership or investment interest not reported as required under the act. The total amount of civil monetary penalties imposed under this subsection is limited to \$204,384.⁵

Knowing violations are currently penalized at not less than \$13,625, but not more than \$136,258, for each payment or other transfer of value or ownership or investment interest not reported. The total amount of civil monetary penalties imposed under this section with respect to each annual submission of information by a reporting entity is limited to \$1,362,567.⁶

Therefore, the total potential liability of both knowing and unknowing violations under the PPSA can be up to \$1,566,951 annually.

Updates to the PPSA

The PPSA continues to evolve in order to effectively discourage fraudulent behavior in the industry.

On June 30, 2024, data from Calendar Year 2023 will reflect updates that were finalized in the Calendar Year 2022 Physician Fee Schedule.⁷ In part, this includes the addition of a mandatory payment context field for records attributed to teaching hospitals, and also requires reporting entities to update their contact information. There is an addition of the option for reporting entities to recertify annually, even when no records are being reported. The new rule disallows record deletions without a substantiated reason, as well as publication delays for general payment records. The changes also clarify the exception for short-term loans to state that the exception applies for 90 total days in a calendar year, regardless of whether the 90 days were consecutive. The changes remove the option to submit and attest to general payment records with an "ownership" nature of payment category. The rules also include an added definition for physician-owned distributorships as a subset of applicable manufacturers and group purchasing organizations, and an updated definition of ownership interest.

Other revisions since the enactment of the PPSA include three additional "nature of payment" categories: acquisitions, debt forgiveness, and long-term medical supply or device loan. Similarly, the previous two education categories were consolidated into one: compensation for serving as faculty or as a speaker for a medical education program. These changes took effect in 2022. Previously, the 2021 Support Act enabled Open Payments to include physician's assistants, nurse practitioners, certified registered nurse anesthetists, and certified nurse midwives in the definition of "covered recipient" in order to address concerns.⁸ It also allowed CMS to public NPI numbers within the Open Payments Data.

Covered entities must stay up to date on the evolution of the PPSA in order to remain in compliance with their reporting obligations each year. Despite initial Department of Justice enforcement, there have not been any public enforcement actions since 2021. The three public settlements are discussed below.

Enforcement Summary

The United States Department of Justice settled its first enforcement action in October 2020 against Medtronic USA Inc. The settlement was the result of an investigation by the Civil Division of the Department of Justice, the U.S. Attorney's Office for the District of South Dakota, and the Office of Inspector General. The settlement resolved claims of liability under of the False Claims Act, the Anti-Kickback Statute, and reporting violations under CMS Open Payments Program as required by the PPSA.

Specifically, Medtronic was alleged to have been involved in a scheme with neurosurgeon Wilson Asfora, MD. The government claimed that Medtronic paid for more than one hundred social events with expensive food and drinks attended by Asfora's potential and existing referral sources at a restaurant that Medtronic knew Asfora owned in order to induce Asfora "to use Medtronic's SynchroMed II intrathecal infusion pumps."

In addition to the kickback scheme, the government alleged that Medtronic "violated the Open Payments Program by failing to accurately report payments it made" to Asfora to CMS. The investigation determined that despite Medtronic knowingly making payments to Asfora's restaurant at his request, the company underreported those transfers of value to CMS. According to the government, rather than reporting the total amount paid to Asfora and his restaurant as required by the Sunshine Act at the time, Medtronic only reported the attributed value of the food and drinks that each individual physician at the event consumed, leading to a severely diminished total reported. The current rule requires that applicable manufacturers calculate the value per person by dividing the entire cost of the food or beverage by the total number of individuals who partook in the meal.⁹

Medtronic agreed to pay over \$9.2 million: \$8.1 million to resolve violations of the False Claims Act and \$1.1 million to resolve the violations of the Open Payments Program.¹⁰ At the time, the PPSA limited the total civil monetary penalties for failure to fully report to CMS to a total of \$1.15 million annually. In this case, the agreement penalty amount of \$1.1 million served as aggressive precedent by nearing the maximum annual penalty.

In May 2021, months after the release of the Medtronic settlement, the Department of Justice released the settlement and penalties for Dr. Wilson Asfora's role in the alleged Medtronic scheme. Asfora and the two medical device distributorships he owned, Medical Designs LLC and Sicage LLC, agreed to pay \$4.4 million total in order to resolve False Claims Act and Anti-Kickback Statute allegations. Both companies were also required to pay an additional \$100,000 as a penalty for the Open Payments Program violations for failing to report Asfora's ownership interests and payments made by the companies to the neurosurgeon.¹¹

On May 19, 2021, the Department of Justice announced another Open Payments Program settlement arising from private qui tam litigation in the Eastern District of Pennsylvania. The settlement was "among the first settlements to resolve allegations under both the False Claims Act and the Open Payments Program" as encouraged by the Senate Finance Committee's March 2019 request to investigate and pursue noncompliance with the PPSA.

The settlement was the result of qui tam allegations that Medicrea, a small French medical device manufacturer, and its United States affiliate, Medicrea USA Inc., violated the Anti-Kickback Statute by hosting United States physicians

at a 2013 Scoliosis Research Society's conference in Lyon, France. At this conference, Medicrea allegedly provided value to the physicians "in the form of meals, alcoholic beverages, entertainment, and travel expenses" in order to induce physicians to purchase their spinal devices that was the sole source of revenue for the company.¹² The settlement also resolved the associated Open Payments Program violation allegations that Medicrea failed to fully report these physician entertainment expenses to CMS.

The settlement resolved alleged claims and did not determine any liability of Medicrea or any of its employees. As a result of the agreement, Medicrea paid \$1 million to the United States and participating states for resolution of the False Claims Act and the Anti-Kickback Statute allegations as well as an additional \$1 million to the United States for alleged violation of the Open Payments Program.¹³

Although there has been a lapse in public settlements since 2021, reporting entities may be audited by CMS. Reporting entities are required to keep all records related to financial transactions with covered recipients for at least five years after publication.



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Endnotes

¹42 CFR § 403.904(c).

²42 CFR § 403.904(f).

³42 CFR § 403.906.

⁴42 CFR § 403.908; See "Search Open Payments," U.S.

Centers for Medicare & Medicaid Services, accessed

May 13, 2024, <https://openpaymentsdata.cms.gov/>.

⁵42 CFR § 403.912.

⁶*Id.*

⁷See 86 FR 64996.

⁸See 42 CFR § 403.902.

⁹See 42 CFR § 403.904 (g).

¹⁰U.S. Department of Justice, "Medtronic to Pay Over \$9.2 Million To Settle Allegations of Improper Payments to South Dakota Neurosurgeon," news release, October 29, 2020, <https://www.justice.gov/opa/pr/medtronic-pay-over-92-million-settle-allegations-improper-pay->